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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,198	11/30/2000	Pierre L. Triozzi	CIR 2-005	2840

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EXAMINER	
WINKLER, ULRIKE 10	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/727,198	TRIOZZI ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *9-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 56-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The Amendment filed December 23, 2002 (Paper No. 9) in response to the Office Action of June 18, 2002 is acknowledged and has been entered. Claims 1-66 are pending and claims 1-8 and 57-66 are currently being examined. Upon review and reconsideration of Applicant's traversal in view of Applicant's amendment to claim 1, clarifying that fractions greater than 50 kDa are contemplated in the claims is persuasive. Therefore the restriction among groups 1, 2, 13 and 15 of Paper No. 5 **is withdrawn** and claims 1-8 and 57-66 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Double Patenting

The rejection of Claims 1-5, 8 and rejoined claims 6, 7 and 57-66 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 12, 14, 17 and 18 of U.S. Patent No. 6,093,381 **is maintained** for reason of record.

Applicant's response and arguments have been fully considered but are not deemed persuasive. Applicant's have amended claim 1 indicating that the factor "consists essentially of a greater than 50 kDa fraction". It is noted that Applicant did not amendment claim 57 which "comprises a greater than 50 kDa fraction". The MPEP provides guidelines for treating transitional claim language (see below). In this instance Applicant's amendment to the claims does not alter the prior rejection because the transitional phrase "consists essentially of" is

interpreted as "comprising". The second limitation of "therapeutic fraction" does not add any structural limitations, as it does not specifically exclude proteins that are less than 50 kDa in size.

Applicants have not gone on the record stating unequivocally that proteins less than 50 kDa in size are specifically excluded in the instant invention. Furthermore the specification on page 29, lines 10-12 indicates that the "factor C" may be composed of multiple components implying that components that are less than 50 kDa in size may be included with the factor. The burden is on applicant in showing that the additional elements, i.e. proteins that are less than 50 kDa in size have a negative effect on the characteristic of the instantly claimed factor in order for these smaller proteins to be excluded from the instant invention.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed at treating a patient afflicted with a disease - cancer- comprising a greater than 50kDa fraction of a supernatant from mitogenically stimulated lymph node lymphocytes. The factor is obtained from cells stimulated with IL-2 and anti-CD-3 Ab. The patented claims are drawn to a whole supernatant fraction from lymph node cells stimulated with IL-2 and anti-CD-3 Ab. The patented claims are drawn to improving the treatment of cancer patients utilizing this supernatant which inherently contains the greater than 50kDa fraction. The limitation of "treating patients" is broad and includes combination therapies as found in claims 11, 12, 14, 17 and 18 of U.S. Patent No. 6,093,381. Therefore, the instant rejection is maintained.

Claim Rejections - 35 USC § 102

The rejection of claims 1-5, 8 and rejoined claims 6, 7, 57-66 under 35 U.S.C. 102(a) or 35 U.S.C. 102(e) as being anticipated by Triozzi et al. (U.S. Pat. No. 6,093,381) **is maintained** for reasons of record.

Applicant's response and arguments have been fully considered but are not deemed persuasive. Specifically applicant has amended claim 1 indicating that the factor "consists essentially of a greater than 50 kDa fraction". It is noted that applicant did not amendment claim 57 which "comprises a greater than 50 kDa fraction". The second limitation of "therapeutic fraction" does not any structural structural limitations, as it does not specifically exclude proteins that are less than 50 kDa in size. The MPEP provides the following guidelines for treating transitional claim language.

> MPEP 2100 The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas *Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco*, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). **For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."** See, e.g., *PPG*, 156 F.3d at 1355, 48

> USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of **"consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention.** *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language.").

In this instance applicants amendment to the claims does not alter the prior rejection because the transitional phrase "consists essentially of" is interpreted "comprising". Applicants have not gone on the record stating unequivocally that proteins less than 50 kDa in size are specifically excluded in the instant invention. Furthermore the specification on page 29, lines 10-12 indicates that the "factor C" may be composed of multiple components implying that components that are less than 50 kDa in size may be included with the factor. The burden is on applicant in showing that he additional elements, i.e. proteins that are less than 50 kDa in size have a negative effect on the characteristic of the instantly claimed factor in order for these smaller proteins to be excluded from the instant invention. Triozzi et al. disclose a supernatant derived from cancer patient lymph node lymphocytes that are stimulated with IL-2 and anti-CD3 Ab. The supernatant contains all molecular weight fractions including those that are greater than or equal to 50kDa. The reference discloses using the supernatant as a treatment. Therefore , the rejection is maintained.

The rejection of claims 1 and 5 and rejoined claims 57 and 61 under 35 U.S.C. 102(b) as being anticipated by Chang et al. (U.S. Pat. No. 4,596,774) **is maintained** for reasons of record.

Applicant's response and arguments have been fully considered but are not deemed persuasive. Applicant's have amended claim 1 indicating that the factor "consists essentially of a greater than 50 kDa fraction". It is noted that Applicant did not amendment claim 57 which "comprises a greater than 50 kDa fraction". The MPEP provides guidelines for treating transitional claim language (see above).

In this instance Applicant's amendment to the claims does not alter the prior rejection because the transitional phrase "consists essentially of" is interpreted as "comprising". Applicants have not gone on the record stating unequivocally that proteins less than 50 kDa in size are specifically excluded in the instant invention. Furthermore the specification on page 29, lines 10-12 indicates that the "factor C" may be composed of multiple components implying that components that are less than 50 kDa in size may be included with the factor. The burden is on applicant in showing that the additional elements, i.e. proteins that are less than 50 kDa in size have a negative effect on the characteristic of the instantly claimed factor in order for these smaller proteins to be excluded from the instant invention. Chang et al. disclose the methods of preparing cell-free products (supernatant) from stimulated peripheral blood lymphocytes. The supernatant contains all molecular weight fractions including those that are greater than or equal to 50kDa (see figure 5). The reference discloses using the supernatant as a treatment. Therefore, the rejection is maintained.

The rejection of claims 1-3 and rejoined claims 57-59 under 35 U.S.C. 102(b) as being anticipated by Triozzi et al. (AIDS Reasearch and Human Retrovirus, 1998) **is maintained** for reason of record.

Applicant's response and arguments have been fully considered but are not deemed persuasive. Applicant's have amended claim 1 indicating that the factor "consists essentially of a greater than 50 kDa fraction". It is noted that Applicant did not amendment claim 57 which "comprises a greater than 50 kDa fraction". The MPEP provides guidelines for treating transitional claim language (see above).

In this instance Applicant's amendment to the claims does not alter the prior rejection because the transitional phrase "consists essentially of" is interpreted as "comprising". Applicants have not gone on the record stating unequivocally that proteins less than 50 kDa in size are specifically excluded in the instant invention. Furthermore the specification on page 29, lines 10-12 indicates that the "factor C" may be composed of multiple components implying that components that are less than 50 kDa in size may be included with the factor. The burden is on applicant in showing that the additional elements, i.e. proteins that are less than 50 kDa in size have a negative effect on the characteristic of the instantly claimed factor in order for these smaller proteins to be excluded from the instant invention. Triozzi et al. disclose mitogen stimulated lymph node lymphocytes for preparing cell-free products (supernatants). The supernatant contains all molecular weight fractions including those that are greater than or equal to 50kDa (see page 645- HIV-1 suppression). The reference discloses using the supernatant as a treatment. Therefore, the rejection is maintained.

The rejection of claims 1, 5, 8 under 35 U.S.C. 102(b) as being anticipated by Tanaka et al. (EMBO Journal, 1995) **is withdrawn** in view of Applicant's arguments that the specification has specifically pointed out that sFasL is not an active component of the factor.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

James C. Housel

JAMES HOUSEL 3/10/03
SUPERVISORY PATENT EXAMINER
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